SCHEDULE 1

Regulation 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

Interpretation

1. In this Schedule, "the 2012 Regulations" means the Human Medicines Regulations 2012 [M1].

Commencement Information

I1 Sch. 1 para. 1 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 S.I. 2012/1916; relevant amendments were made by S.I. 2019/775.

PROSPECTIVE

Amendment of regulation 15 (amendment of regulation 18 of the 2012 Regulations – wholesale dealing in medicinal products)

[F1]**2.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 17 (amendment of regulation 19 of the 2012 Regulations – exemptions from requirement for wholesale dealer's licence)

[F1]**3.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 47 (amendment of regulation 48 of the 2012 Regulations – application of Part 5)

[F1]**4.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 56 (substitution of regulation 51 of the 2012 Regulations - applications relating to generic medicinal products)

[F1]**5.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 58 (amendment of regulation 53 of the 2012 Regulations - applications relating to similar biological medicinal products)

[F1]**6.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

Amendment of regulation 63 (amendment of Schedule 11 to the 2012 Regulations – advice and representations)

7.—(1) Regulation 63 is amended as follows.

(2) For paragraph (2)(a)(ii) substitute—

"(ii) at the end insert—

"and;

(d) a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.";".

(3) After paragraph (2) insert—

"(2A) In paragraph 2 (requirement to consult the appropriate committee), after sub-paragraph (2), insert—

"(2A) The licensing authority must consult the appropriate committee if the authority proposes to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.".

(2B) In paragraph 3 (exceptions to requirement to consult)—

(a) in sub-paragraph (1), after "traditional herbal registration" insert " , or to a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation, "; and

(b) in sub-paragraph (1)(a), after "determined", insert " or the decision to be made ".

(2C) In paragraph 5 (provisional opinion against authorisation)—

(a) after sub-paragraph (2), insert—

"(2A) If the appropriate committee is consulted under paragraph 2(2A), it may give a provisional opinion that it may be unable to advise the licensing authority to decide that the orphan criteria are met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation."; and

(b) in sub-paragraph (3), after "grant or renewal", insert " , the applicant intending to demonstrate that the orphan criteria are met in relation to a medicinal product, ".

(2D) In paragraph 10 (decision of licensing authority)—

(a) omit the "or" at the end of sub-paragraph (1)(b); and

(b) at the end of sub-paragraph (1)(c) insert—

"; or

(d) decide whether to proceed with its proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation,".".

(4) For paragraph (3) substitute—

"(3) In paragraph 12 (licensing authority decisions in other cases)—

(a) in sub-paragraph (1), insert " , parallel import licence " after " UK marketing authorisation " in each place it appears;

(b) in sub-paragraph (5), insert " , licence " after " the authorisation "; and

(c) after sub-paragraph (4), insert—

"(4A) This paragraph also applies if, having been consulted under paragraph 2(2A), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2A) and the licensing authority proposes to decide, against that committee's advice, that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.".".

(5) After paragraph (3) insert—

"(3A) After Part 1 insert—

"PART 1A

Paediatric Decisions

Application of this Part

13A. This Part applies to a proposed decision by the licensing authority—

(a) to refuse to agree a paediatric investigation plan (including a waiver or deferral proposed to be included in that plan), or to agree such a plan otherwise than in accordance with the request for agreement;

(b) to refuse to agree a modification to a paediatric investigation plan (including a waiver or deferral which is, or is proposed to be, included in that plan), or to agree such a modification otherwise than in accordance with the request for the modification;

(c) to impose, revoke or refuse to grant a waiver of the obligation under regulation 50A(3) to provide to the licensing authority the results of all

studies performed, and details of all information collected, in compliance with an agreed paediatric investigation plan; or

(d) to revoke a waiver which was agreed as part of an agreed paediatric investigation plan.

Opportunity to make representations

13B.—(1) If the licensing authority proposes to make a decision to which this Part applies, the licensing authority must notify the person to whom the proposed decision would be addressed ("the applicant").

(2) The applicant may, by notice in writing to the licensing authority, request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request before the end of the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant's request.

Written representations

13C.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may at the request of the applicant extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

13D.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

13E.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

13F.—(1) The licensing authority must decide whether to proceed with its proposed decision—

(a) if the applicant requested the opportunity to make written or oral representations, after receiving the appropriate committee's report under paragraph 13C or 13D or notification under paragraph 13E; or

(b) if the applicant did not request the opportunity to make written or oral representations, after the expiry of the period of time for notifying a request for that opportunity.

(2) If the appropriate committee gives a report under paragraph 13C or 13D, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 13F notification

13G.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 13F.

(2) The applicant may notify the licensing authority in writing that the applicant wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification before the end of the period of 28 days beginning with the day on which the notification is given to the applicant under paragraph 13F or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the applicant has not made any representations in accordance with paragraph 13C or 13D.".".

Commencement Information

I2 Sch. 1 para. 7 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 139 (amendment of regulation 177 of the 2012 Regulations – application of Part 11 (pharmacovigilance) and interpretation)

F2**8.** . . . . . .

F2 Sch. 1 para. 8 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(b)**

Amendment of Schedule 6 (insertion of Schedule 12A into the 2012 Regulations)

9. In Schedule 6, in Part 8 of inserted Schedule 12A to the 2012 Regulations (periodic safety update reports), in paragraph 27 (format of periodic safety update reports)—

(a) re-number the existing paragraph as sub-paragraph (1) of paragraph 27; and

(b) insert at the end—

"(2) In this paragraph, "signal evaluation" means the process of further evaluating a validated signal taking into account all available evidence, to determine whether there are new risks causally associated with the active substance or medicinal product, or whether known risks have changed, and that process—

(a) may include non-clinical and clinical data; and

(b) must be as comprehensive as possible regarding the sources of information used for that process.".

Commencement Information

I3 Sch. 1 para. 9 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 7 (insertion of Schedule 33A into the 2012 Regulations)

10.—(1) Schedule 7 is amended as follows.

(2) In paragraph 5 of inserted Schedule 33A to the 2012 Regulations (list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day), after paragraph (e) insert—

"(ea) Republic of Korea;".

F3(3) . . . . . .

F4(4) . . . . . .

F3 Sch. 1 para. 10(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(c)**

F4 Sch. 1 para. 10(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(c)**

Commencement Information

I4 Sch. 1 para. 10 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Status:
This version of this schedule contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 1.